Remarks

Claim Amendments

The claims have been amended as follows. Claim 1 has been amended to state that the bioactive agent described in the claim is hemostatic. Support for this limitation may be found in the specification as filed at least at page 9, line 5 through page 11, line 20.

Claim Rejections – 35 U.S.C. § 103

In the most recent Office Action, the Examiner rejected claims 1, 3, 6-7, 10-11, 13, 16-17, and 21-43 under 35 U.S.C. § 103(a) as being unpatentable over Guire (4,979,959) in view of Marin et al. (5,433,477). The Examiner contends that Guire discloses a vascular graft with a thrombogenic agent covalently bonded to its surface by the activation of covalent groups. The Examiner further contends that Marin et al. teaches the use of a vascular graft as part of an endovascular stent-graft and that the combination of these teachings would have been obvious to one of ordinary skill in the art.

Applicants respectfully traverse the rejection of the above claims under 35 U.S.C. § 103(a) because the references fail to address all of the limitations of independent claims 1, 10, 11, 21, and 31 and the combination of these references would not be undertaken by a person of ordinary skill in the art, thereby demonstrating a lack of motivation to combine.

As discussed in the Affidavit of David Clapper enclosed herein and incorporated by reference, concerns about perigraft leaking—leaking around or through an endovascular graft—have limited the use of endovascular graft therapies. The prior art does not show coatings of any type on endovascular grafts to address perigraft leaking. Though endovascular grafts are not known to be coated in the art, clinicians are familiar with reducing through-graft leaking in other grafts by coating them with protein (e.g. albumin, collagen) to physically plug pores in the graft. Such coatings stiffen the graft and thereby reduce pliability. Because the experience of those of ordinary skill in the art of making endovascular grafts, as well as surgeons who install the grafts, has been that the application of coatings to any graft structure to reduce through-graft leaking

reduces the pliability of the graft, it is not surprising that prior to this invention endovascular grafts were not coated to attempt to reduce perigraft leaking. Therefore, those of skill in the art would expect that an endovascular graft coated with coatings known in the art to reduce leaking could not be safely fed through a blood vessel to the location in need of repair due to the rigidity caused by the coating. The unexpected result that the grafts of the invention remain incredibly pliable and can be safely fed through a blood vessel was described on pages 16 and 17 of the application as filed:

> A coating of the present invention will typically not add significantly to the bulk of the graft, or interfere with its delivery via a catheter. Nor, in turn, will it interfere with (and preferably will enhance) long term ingrowth by fibrous tissue. Surprisingly, it has been found that bioactive agents can be coated in a manner that provides suitable physical qualities (e.g., bulk, tenacity), chemical qualities (e.g., biocompatibility), and biological qualitites (e.g., hemostatic activity) sufficient to lessen or avoid endoleaking yet permit the graft to be delivered and positioned in a minimally invasive fashion (typically, through a catheter).

Page 16 Line 20 to Page 17 Line 3.

Furthermore, those of skill in the art also believed that because endovascular grafts are installed within the lumen of a blood vessel, particularly vessels having smaller diameters, problems may arise including increased turbulence in the blood flow within the vessel and unacceptable thrombotic response that may restrict blood flow, narrow the vessel lumen and possibly occlude the vessel over time. Therefore, it was counterintuitive to those of ordinary skill in the art to consider putting a hemostatic coating on an endovascular graft because of the possibility of exacerbating the described problems that may occur due to a hemostatic response at the graft site.

Pending claims are limited to a stent graft comprising an expandable stent and stent cover portion having a bioactive agent that is hemostatic. The hemostatic coating on the endovascular grafts of embodiments of the invention causes a fibrous tissue ingrowth when the graft is implanted within the lumen of a vessel. These types of coatings are normally discouraged from use in a vascular graft because of the fibrotic response, which may cause occlusion of the typically smaller diameter vascular graft. This fibrotic response is unexpectedly advantageous in endovascular graft applications because it may result in the filling of the perigraft region with stable tissue such as smooth muscle cells or fibroblasts. This surprising result is not suggested

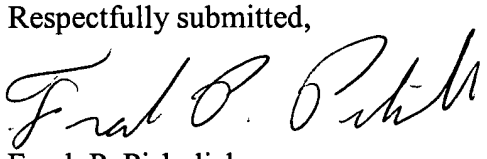
by the prior art. Furthermore, coating an endovascular graft with a hemostatic agent is the opposite of what one skilled in the art having access to Marin and Guire would have been motivated to do.

Claims 1, 10-11, 21, and 31 are allowable over the cited art for at least the reasons discussed above. Dependent claims 3, 6-7, 16-17, 22-30, and 32-43 are also allowable as depending, either directly or indirectly, from the allowable independent claims. It is noted that the dependent claims in the application also contain additional limitations and combinations of limitations not disclosed in the cited references. As previously mentioned in the response dated April 12, 2005, rejections of the independent claims do not necessarily address the limitations found in the dependent claims. The claims are presumed patentable unless the cited art discloses or makes obvious the claimed subject matter.

In light of the above, the Applicants submit that each of claims 1, 3, 6-7, 10-11, 16-17, and 21-43 is in condition for allowance. As these are the only claims pending in the application, prompt issuance of a Notice of Allowance in this case is courteously solicited. If the Examiner feels that prosecution of the present application can be materially advanced by a telephonic interview, the undersigned would welcome a call at the number listed below.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,



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